

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

TAMMY ALLEN, PERSONAL REPRESENTATIVE
OF THE ESTATE OF NORMAN ALLEN

Plaintiff,

v.

UNITED STATES OF AMERICA

Defendant.

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) Case No. 05-11463-DPW
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AFFIDAVIT OF JAMES RICHTER, M.D.

I submit the following Affidavit regarding the facts of this case and my expert medical opinion that I am prepared to offer at the trial of this matter.

1. It is my professional opinion within a reasonable degree of medical certainty that the care provided to Mr. Allen by Dr. Kelly conformed to the standards of practice of an average qualified primary care physician from 1997-2000. Primary care physicians were not required to administer colorectal cancer screenings during this time period. While national professional organizations, such as the American Cancer Society and the American Gastroenterological Association, recommended colorectal cancer screenings, these recommendations are goals for the medical world; they are not standards of care. A standard of care should be evaluated according to what the average doctor does, and in my professional opinion, the average physician from 1997-2000 did not regularly screen for colorectal cancers in patients with ailments similar to those of Norman Allen.

2. I am licensed to practice medicine in Massachusetts, and I am certified in both internal medicine and gastroenterology by the American Board of Internal Medicine. I practice internal medicine and gastroenterology, and I am familiar with the standard of practice of the average qualified primary care physician for screening for colorectal cancer at the times in question.

3. I have reviewed the documents provided to me, including the records of the care provided by Dr. Michael Kelly to Mr. Norman Allen, the depositions of Dr. Kelly and Mrs. Allen, and the expert opinions of Drs. Ratner and Neugut and the subsequent allegations of negligent medical care.

4. Mr. Allen first consulted Dr. Kelly at the Greater Lawrence Family Health Center on January 5, 1996. At this visit a family medical history was obtained. Mr. Allen did not inform the clinic that his father allegedly suffered from colorectal cancer. As also evident in the record, Dr. Kelly was aware of Mr. Allen's father's myocardial infarctions and Mr. Allen's mother's asthma. Based on this information, I do not believe Dr. Kelly had any reason to know Mr.

Allen's father allegedly battled with colorectal cancer. Without this information, there was little reason to label Mr. Allen at high-risk for colorectal cancer at this time.

5. Mr. Allen subsequently had a spectrum of interactions with the health center staff for depression, joint and muscular pain, insomnia, presyncope, memory loss, alcohol abuse, and a seizure disorder and was treated with dilantin, Xanax, neurontin, codeine, Paxil, Zoloft, Ambien, Disalsid, Ultram, and temazepam. He continued to smoke heavily and drink alcohol.

6. Mr. Allen consulted Dr. Kelly on March 21, 1997 for muscular pain and possible rheumatoid arthritis. He returned to Dr. Kelly on March 27, 1997. On December 4, 1997 he was seen for arthralgias and shoulder pain. On January 29, 1998 there was a visit for insomnia and cough. On February 27, 1998 he was seen for arthralgias and referred to BMC. He returned on September 3, 1998 and they discussed his seizure disorder. On September 3, 1998 there was an office follow up for seizures and fibromyalgia.

7. On April 6, 1999 Mr. Allen again consulted Dr. Kelly about his insomnia and muscular pain. He reported frequent bowel movements and a 6-pound weight loss since January. Mr. Allen was very depressed and suffered from memory problems. He was smoking 2 to 3 packs of cigarettes per day. Dr. Kelly performed a comprehensive examination and prescribed Ultram for his pain. Dr. Kelly's note reasonably infers that his pain effected his sleep, thereby exacerbating his depression and weight loss.

8. On July 13, 1999 Mr. Allen consulted Dr. Robert Simms for fibromyalgia. Dr. Simms noted lower intestinal bleeding and recommended additional evaluation. He also confirmed the diagnosis of significant depression and recommended psychiatric evaluation.

9. On August 3, 1999 Mr. Allen visited Dr. Kelly complaining of back pain. No note in Dr. Kelly's file mentions that Mr. Allen complained of lower intestinal bleeding. Also, there is no indication in the record that Dr. Kelly received Dr. Simms' report on or before August 3, 1999.

10. On September 27, 1999 Mr. Allen consulted Dr. David Farzan who noted a family history of rectal cancer. This family history of rectal cancer was not reported when Mr. Allen was first seen at the Lawrence Family Health Center. Mr. Allen was then referred to Dr. Thomas Fazio who, in October 1999, performed a colonoscopy demonstrating an advanced 6 to 8 centimeter rectal cancer. At this time, Mr. Allen's cancer was very advanced at Stage III with a lymph node metastasis. Although early diagnosis of colorectal cancer is associated with a tumor at a more favorable stage and outcome of treatment, colorectal cancer is very slow growing and advances over periods of years. It is likely that it had spread well and was already incurable before the April or August 1999 office visits.

11. There is no evidence that Mr. Allen consulted Dr. Kelly specifically for health maintenance. The majority of Mr. Allen's visits to Dr. Kelly were focused on his urgent muscular, sleep and emotional issues leaving little opportunity for addressing other health improvement topics. My professional opinion with a reasonable degree of medical certainty is that colorectal cancer screening was not required and that Dr. Kelly's actions complied with the standard of care for the averaged qualified primary care physician.

12. It is not documented that Dr. Kelly ever recommended colorectal cancer screening. It is my professional opinion within a reasonable degree of medical certainty that is not the standard of practice for doctors to routinely document recommendations.

13. Several national professional organizations (including the American Cancer Society and American Gastroenterological Association) recommended one of three other screening strategies: fecal occult blood testing plus sigmoidoscopy, barium enema, and colonoscopy. These tests were recommended each at variable intervals. The screening recommendations were not established as the standard of practice at that time. These recommendations were goals for the medical field. They were not routinely recommended by the average doctor, which is what the standard of care is based on.

14. The majority of average risk patient between ages 50 to 80 years who have a relationship with an average qualified primary care physician would not have been screened for colorectal cancer between 1997 and 1999, when Dr. Kelly cared for Mr. Allen. *See*, Morbidity and Mortality Weekly Report (Vol. 52, No. 10: 193-196). Medicare has covered colorectal cancer screening tests and procedures since 1998, but use of this benefit has been low. Medicare claims from 1998 - 2002 suggest that only about 31% of beneficiaries have ever had any colorectal cancer-screening test. Between 1998-2001, the relevant period for this case, Medicare only covered screening of high-risk patients. Medicare and Medicaid did not begin to routinely cover the cost of the procedure until 2001. Mr. Allen was not known to be in a high risk patient group.

15. Before Mr. Allen's 50th birthday, he did not have any colorectal symptoms to indicate evaluation for other purposes. My professional opinion with a reasonable degree of medical certainty is that colorectal cancer screening was not required and that Dr. Kelly's actions complied with the standard of care for the averaged qualified primary care physician.

16. At the age of 50 screening for colorectal cancer is recommended, but not accepted as the standard of care. For a variety of reasons, patients often did not consider colon cancer a major risk, and those that did were apprehensive about painful and potentially dangerous procedures. In addition, the majority of patients who were screened in 1997 through 1999 did not complete their examinations until they were 52 or older, which would not have diagnosed Mr. Allen's tumor in time to make a material change in his prognosis. My professional opinion with a reasonable degree of medical certainty is that colorectal cancer screening was not required even after Mr. Allen turned 50 and that Dr. Kelly's actions complied with the standard of care for the averaged qualified primary care physician.

17. It is my professional opinion within a reasonable degree of medical certainty that the care provided to Mr. Allen by Dr. Kelly conformed to the standards of practice of the average qualified primary care physician from 1997-1999, principally because practicing physicians had not adopted the recommendations of expert panels. In addition, patients and insurers had not adopted the recommendations of expert panels. In addition, if the hypothesized examinations had been performed earlier it is more likely that not that it would not had changed the eventual outcome.

Sworn to under the pains and penalties of perjury this day of February, 2007.

Sincerely yours,

James M. Richter, M.D.

On this ____ day of _____, 2007, before me, the undersigned notary public, personally appeared _____ (name of document signer), proved to me through satisfactory evidence of identification, which were _____, to be the person whose name is signed on the preceding or attached document in my presence.

(official signature and seal of notary)

My commission expires _____